

OFFICE OF EXTRAMURAL RESEARCH NOTICE REGARDING ANIMAL
WELFARE DOCUMENTS SUBMITTED TO THE OFFICE OF LABORATORY
ANIMAL WELFARE

RELEASE DATE: July 13, 2004

NOTICE: NOT-OD-04-052

National Institutes of Health (NIH)

This notice informs NIH awardee institutions holding Animal Welfare Assurances in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy, <http://grants.nih.gov/grants/olaw/references/phspol.htm>) of changes related to two required documents. The Office of Laboratory Animal Welfare (OLAW) will now approve Animal Welfare Assurances for periods of up to four years. To promote consistent reporting periods OLAW now strongly encourages awardee institutions to use the calendar year for the reporting period of annual reports. Annual report due dates are also now standardized.

BACKGROUND

Assurances: PHS Policy requires that approval of an assurance will be for a specified period but no longer than five years (IV.A.). Since 1989 OLAW has approved most assurances for periods of five years. Negotiation of a renewal assurance between OLAW and an institution may take several months. OLAW has traditionally administratively extended the approval period of an assurance during the negotiation process. Unless there are indicators to the contrary, OLAW will now approve assurances for periods of up to four years to allow time for the review and approval of renewal assurances. In accordance with PHS Policy, OLAW retains authority to limit the period during which any particular Assurance is effective, or otherwise condition, restrict, or withdraw approval.

Annual Reports: PHS Policy requires that at least once every 12 months the Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, report certain information in writing to OLAW (IV.F.). This information consists of any change in the institution's program of animal care and use, in the Institutional Official and in the IACUC membership, the dates that the IACUC conducted its semiannual evaluations of the program and facilities, and any minority views to reports submitted under IV.F. In most cases, institutions report on the anniversary of the approval of their assurance. In December 1999, NIH announced that institutions could change the date that they report in order to synchronize the date with other annual reporting requirements, e.g., United States Department of Agriculture and the Association for Assessment and Accreditation of Laboratory Animal Care International (NIH Guide Notice OD-00-007, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-007.html>).

OLAW has determined that consistent reporting periods and standardized due dates will allow OLAW to be more responsive to the research community and will help institutions track and comply with reporting requirements. Although institutional flexibility to change the reporting period (and consequently the due date) remains unaffected, OLAW strongly encourages institutions to use the calendar year (January 1- December 31) as the reporting period. To standardize due dates, all annual reports are due to OLAW by the last day of the month immediately following the end of the institution's reporting period.

Guidance regarding implementation of these changes is as follows:

ANIMAL WELFARE ASSURANCE APPROVAL PERIODS

OLAW will approve assurances for periods of up to four years. Renewal assurances must be submitted to OLAW by the expiration date of the assurance. In most cases OLAW expects that it will administratively extend the approval date of the assurance while the renewal is under negotiation, up to five years as allowed by the PHS Policy. It is incumbent upon the institution to actively participate in the negotiation process so that the renewal assurance may be approved in a timely manner. Institutions are reminded that without a valid PHS-approved assurance an institution may not conduct PHS-supported research or other activities involving live vertebrate animals.

Institutions that currently have an assurance with a five-year approval period will be requested to submit their renewal 6-12 months prior to the expiration date in order for the renewal to be negotiated and approved within the PHS Policy timeframe.

ANNUAL REPORTING PERIODS AND ANNUAL REPORT DUE DATES

OLAW strongly encourages institutions to use the calendar year (January 1 - December 31) as the reporting period. Institutions that prefer to use a different 12-month reporting period may do so by submitting a letter or email to OLAW by January 31, 2005, indicating the institution's preferred reporting period. If institutions do not elect a reporting period other than the calendar year, OLAW will consider that the institution is defaulting to using the calendar year as its reporting period.

To implement a calendar year reporting period, the following guidance is provided:

- o Institutions that submitted a report between January 1, 2004 and July 15, 2004 should submit their next annual report by January 31, 2005. The reporting period, for this report only, should be from the end of their last reporting period to December 31, 2004. For example, an institution that submitted an annual report in April 2004 for the period of April 1, 2003 – March 31, 2004 will report by January 31, 2005 for the period of April 1, 2004 - December 31, 2004.

- o Institutions currently scheduled to submit an annual report between July 16, 2004 and December 31, 2004 should wait and submit their next annual report by January 31, 2005. For these institutions, the reporting period will be greater than 12 months for this report

only. For example, an institution scheduled to submit a report in November 2004 for the time period of November 1, 2003 – October 31, 2004, will report by January 31, 2005 for the period of November 1, 2003 - December 31, 2004. Thereafter reports will be due by January 31 of each year for the previous calendar year.

o Institutions that already use the calendar year as their reporting period should submit their next annual report by January 31, 2005.

For institutions that elect to use reporting periods other than the calendar year, the following guidance is provided:

o Submit an email to OLAW at assurances.olaw@od.nih.gov , or write to the Division of Assurances, OLAW, NIH, RKL1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, MD 20892-7982, by January 31, 2005, providing the institution's preferred 12-month reporting period.

o Include the institutional assurance number in the subject line of the email or, if submitting a letter, reference the assurance number (numbers are available at <http://grants.nih.gov/grants/olaw/assurance/300index.htm>).

o The due date for all annual reports, regardless of the reporting period, is the last day of the month immediately following the end of the reporting period, e.g., for the reporting period June 1 – May 31, the report is due June 30.

o The due date for an institution's next annual report must be within 12 months of the submission of the last report to OLAW.

INQUIRIES

For questions or further information, contact:

Office of Laboratory Animal Welfare
Office of Extramural Research
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Department of Health
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